DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 13, 2014

Cybersonics, Inc.
Jeff Vaitekunas
Vice President of R&D
5340 Fryling Road
Erie, PA 16510

Re: K142428
Trade/Device Name: Shock Pulse-SE Lithotripsy System CyberWand II
Regulation Number: 21 CFR 876.4480
Regulation Name: Electrohydraulic Lithotriptor
Regulatory Class: Class II
Product Code: FEO
Dated: August 27, 2014
Received: August 29, 2014

Dear Jeff Vaitekunas,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142428

Device Name
ShockPulse-SE Lithotripsy System

CYBERWAND II

Indications for Use *(Describe)*

The ShockPulse-SE Lithotripsy System is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter and bladder.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

for

ShockPulse-SE Lithotripsy System

(**CYBERWAND** II)

Contact Information for Cybersonics, Inc.

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This Summary was prepared on June 20, 2014.
This Summary was revised on November 12, 2014.

Trade Name

Proprietary:	ShockPulse-SE Lithotripsy System
	CYBERWAND II
Common:	Lithotripter, Ultrasonic Intracorporeal

Classification

Product Code FEO (lithotripter, ultrasonic)
Class II, 21 CFR 876.4480 – Electrohydraulic lithotripter

Predicate Device

The ShockPulse-SE Lithotripsy System (CYBERWAND II) described in this Traditional 510(k) Submission is, in our opinion, substantially equivalent to the predicate device, CyberWand Dual Action Ultrasonic Lithotripsy System (K120303).

Product Description

The ShockPulse-SE Lithotripsy System (CYBERWAND II) is the next generation of the CyberWand System. The ShockPulse-SE is an electromechanical device, whose intended purpose is to fragment and aspirate calculi. The hand piece consists of an ultrasonic transducer containing piezoelectric elements which are driven by a generator operating at approximately 21,000 Hz. The transducer is lightweight and incorporates two contact switches that activate Standard Power and High Power generator output. Activation will either require continuous pushing of the button or a double click to latch activation on; a single click of either button would then turn activation off. There are markings near the buttons to indicate function.

Suction control is integrated into the transducer housing. With a thumb wheel that can rotate approximately 20 degrees, the flow can be varied from “full” on to “off.” There are markings on the transducer to indicate which direction increases and decreases suction flow through the transducer lumen.

There are families of probes that function similar to the probes of the current CyberWand System (K120303) by transmitting stress-waves from the transducer to the calculi to break up kidney-stones. Hollow probes permit simultaneous suction. The direct patient-contact material is stainless steel, which is the same material used in the predicate system.

Indications for Use Statement

The ShockPulse-SE Lithotripsy System (CYBERWAND II) is intended to be used for the fragmentation of urinary tract calculi in the kidney, ureter and bladder.

Substantial Equivalence Rationale

The ShockPulse Lithotripsy System (CYBERWAND II) is substantially equivalent to the:

- CyberWand Dual Action Ultrasonic Lithotripsy System (CYBERWAND) (K120303)

The ShockPulse-SE Lithotripsy System (CYBERWAND II) has the following similarities to the predicate device CyberWand Dual Action Ultrasonic Lithotripsy System that previously received 510(k) clearance (K120303):

- Indications for use
- Free mass enhanced ultrasonic technology
- Basic design
- Patient contact materials

The ShockPulse-SE Lithotripsy System (CYBERWAND II) is the next generation of the CyberWand System. Key differences between the ShockPulse-SE Lithotripsy System and predicate device are:

- Generator:
    - addition of an auto-tune feature (versus manual tuning to match the transducer's resonant frequency),
    - addition of circuitry to provide probe constant probe displacement under various loading conditions, and
    - a redesigned housing to be more ergonomic.
- Transducer:
    - addition of power activation buttons (providing an option to using the footswitch),
    - addition of a suction control knob, and
    - a redesigned housing to be more ergonomic.
- Probes:
    - change from a dual tube probe design to a single tube design, and
    - expanding the previous range of probe sizes (3.76 and 1.65 mm OD) to include four new models (3.40, 1.83, 1.50, and 0.97 mm OD).
- Wrench:
    - the standard wrench was modified to limit the applied torque when attaching the probe to the transducer.

The remaining system components are similar or unchanged: footswitch, nose-cone, and cleaning stylets.

Performance Data

The safety and effectiveness of the ShockPulse SE Lithotripsy System (CYBERWAND II) is determined primarily by confirming that its design and performances conform to the established national and international standards, protocols applicable to lithotripters and the FDA document, "Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters". The ShockPulse-SE Lithotripsy System (CYBERWAND II) performs as well as or

better than the predicate device. The ShockPulse-SE Lithotripsy System (CYBERWAND II) complies with the requirements of each the standards and protocols discussed below.

Performance Considerations

The ShockPulse-SE Lithotripsy System (also known as the CyberWand II) was evaluated extensively for performance using bench-top tests and a series of simulated-use animal labs. Below are outlines of the individual tests performed:

CyberWand II Performance Analysis for Stone Breakage

- Demonstrating the performance (mass removal and stone drilling) of the CyberWand II compared to the predicate CyberWand I.
  - The CyberWand II 3.76 probe drills through a stone at least 10% faster than the CyberWand I 3.76 Dual Probe.
  - The CyberWand II 3.76 probe removes mass at least 20% faster than the CyberWand I 3.76 Dual Probe.
- Demonstrating the retropulsion of the CyberWand II ureteral probe compared to the LithoClast pneumatic. The LithoClast is a competitively marketed lithotripter.
  - The CyberWand II 1.65 probe has less impact force than the LithoClast pneumatic ureteral probe.

Equivalent stone breakage for the smallest probe size (0.97 mm solid probe) is supported by stone breakage measurements and identification of

a reference device with an 0.8 mm ultrasonic probe (K111058, Med-Sonics Corp. UreTron Multi Probe Lithotripter).

CyberWand II Transducer and Torque Wrench Life Cycle Analysis (50 Cycles)

- Demonstrating the transducer and torque wrench performance does not degrade over 50 simulated use cycles and that every aspect of the transducer is functional after 50 simulated use cycles. The following characteristics were evaluated:
    - Performance
        - Mass Removal
        - Drill Rate
        - Probe Tip Displacement
    - Functionality
        - Suction Control
        - Transducer Button Activation Switches
    - Safety
        - Electrical Safety (Patient Leakage Current)
    - Appearance Quality
        - Black Anodize
        - Laser Etching

CyberWand II Probe Reliability and Reusability Analysis

- Demonstrating probes are functional after a single simulated use. This tested for the probes to be capable of 5x typical use time.

  Note: The probes are to be labeled single use.

CyberWand II IEC 61847 Evaluation

- Demonstrating the output characteristics of the CyberWand II system including all probe sizes compared to the CyberWand I 3.76 mm dual probe.
- Demonstrating less probe tip displacement (101 microns peak-to-peak) compared to the predicate CyberWand I (102 microns peak-to-peak) as evidence for a safe and substantially equivalent next generation lithotripter.

Tissue Perforation Testing (Performed on the predicate CyberWand I)

Dr. Evans' Pig Kidney Test

- The Pig Kidney Test supported the safety of the largest probe size (3.76 mm).

- In vitro testing was performed to determine the type of tissue damage induced by the CyberWand Dual Action Ultrasonic Lithotripsy System and LithoClast Ultra when placed in contact with the surface of a freshly harvested porcine kidney. The CyberWand consistently induced less kidney tissue damage than the LithoClast Ultra using a visual assessment methodology.

- The ShockPulse SE system was designed and tested to have equal or less maximum tip amplitude than the CyberWand Dual Action Ultrasonic Lithotripsy System. Further, the CyberWand ShockPulse SE system was tested in simulated use conditions by several physicians in the porcine model; and no significant tissue damage occurred.

- Equivalent tissue perforation potential for the smallest probe size (0.97 mm) is supported by identification of a reference device with an 0.8 mm ultrasonic probe (K111058, Med-Sonics Corp. UreTron Multi Probe Lithotripter).

CyberWand II Torque Wrench Performance

- Demonstrating a consistent torque specification of 35-40 inch pounds.

CyberWand II Generator and Footswitch Life Cycle Analysis

- Demonstrating a useful life of 7 years for the generator.
- Demonstrating footswitch durability and IPX6 rating.

CyberWand II Shipping and Handling Durability Verification and Validation

- Demonstrating system functionality after being run through rigorous simulated shipping and handling.

Noise Evaluation of CyberWand II Transducer

- Demonstrating less noise output of the CyberWand II compared to the CyberWand I.

Surface Temperature Profile of the CyberWand II Aluminum Transducer

- Demonstrating that the surface temperature of the transducer stabilizes at an acceptable level while running with aspiration. The acceptable level is defined by IEC 60601-1.
- Demonstrating that the surface temperature of the CyberWand II transducer stabilizes at a lower temperature than the CyberWand I while running with and without aspiration.

Setup Steps - CyberWand and CyberWand II ShockPulse SE

- Demonstrating the number of setup steps is less for the CyberWand II as compared to the CyberWand I.
  - The CyberWand II has 37.5% fewer steps which saves time in the Operating Room and reduces the probability of improper setup and a delay in procedure

Cybersonics' ShockPulse SE Usability Verification and Validation

- Demonstrating the ability for the CyberWand II 3.76, 1.65, and 0.97 to fragment simulated urinary tract calculi.
- Demonstrating the usability of the CyberWand II IFU and labeling.
- Demonstrating the CyberWand II meets customer needs.

Electrical Safety Considerations

The ShockPulse-SE Lithotripsy System (CYBERWAND II) is classified as IEC Electrical Safety Class I equipment, with a Type BF applied part that complies with IEC 60601-1:2005 3rd Edition. The following is a list of testing related to the evaluation of the ShockPulse-SE Lithotripsy System for Electromagnetic Compatibility and Electrical Safety. All testing was conducted by Intertek.

IEC 60601-1, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance.

Standards: IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)

EMC Test Report

Standards: IEC 60601-1-2 ed3.0 (2007-03) With Voltage Deviations for Japan.

EMC Emissions Report

Standards: Radiated Emissions, CISPR 11:2009+A1:2010 per IEC 60601-1-2 ed3.0 (2007-03).

Classification Constructional Data Report (CDR)

Standards: Medical electrical equipment, Part 1: General Requirements for Basic Safety and Essential Performance, AAMI ES60601-1:2005, Issued: 2006/03/09: 2005 Version (R2012); with AMD C1: 2009, AMD 2: 2010

Medical Electrical Equipment - Part 1: General Req. for Basic Safety & Essential Performance, CSA C22.2#60601-1, Issued: 2008/02/01 Ed: 2; Cor. 2: 2011.

IEC Certificate US/5130/ITS

CB Test Certificate - Compliance with ISO 14971, as required by subclause 4.2, has been established by performing an inspection (desk-top audit) of the Risk Management File.

Standards: ISO 14971, IEC 60601-1-6(ed.3), IEC 60601-1(ed.3), IEC 62366(ed.1).

The purpose of the Electromagnetic Compatibility (EMC) Directive is to ensure the customer that all standards for manufacturing and operating the electronics of the device safely have been adhered to and followed. The EMC Directive also stipulates that the device will not emit radiation at levels that will interfere with other devices located nearby. Additionally, the EMC Directive ensures the device will not transmit electro-magnetic surges back into the power grid at frequencies and amplitudes that are above the values listed in the standard.

Software Validation Considerations

Software validation for the life cycle operation has been performed according to the FDA's Moderate Level of Concern recommendations provided in the document "*Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (5/29/98).*"

Sterilization Validation Considerations

All probes except the SPL-PD376 are provided single patient use, non-sterile, and are cleaned and sterilized prior to use by the user in accordance with the directions provided in the system IFU. The SPL-PD376 probe is packaged sterile, single patient use, and is sterilized using the EO process outlined below.

EO Sterilization for 3.76 mm single probe

MOOG Medical Device Group analyzed the differences between the predicate CyberWand I 3.76 Dual Probe (CW-RBP) and the present SPL-PD376 and has determined that the packaging and sterilization validations apply to the SPL-PD376 probes. The packaging and sterilization for the Shock Pulse SE Lithotripsy System probes are the same as described in K120303.

5 year shelf life sterile packaging

The SPL-PD376 probe is packaged sterile, single patient use, with a 5 year sterility shelf-life. It is sterilized using the EO process outlined above. 5-year shelf life has been assured with both accelerated and real-time ageing and subsequent testing. The 5 year shelf life of the SPL-PD376

probe is also supported by data submitted in reference device K132795. Subsequently real-time ageing was performed.

Cleaning and Steam Sterilization

The ShockPulse SE Lithotripsy System (CYBERWAND II) probes, nose-cone, torque wrench, stylets and transducer are all provided non-sterile to the user, and are to be cleaned and sterilized in accordance with the instructions provided in the system IFU. Cleaning and sterilization validations were performed by MicroTest, and the reports are summarized below.

Cleaning Efficacy

Demonstrating a validated manual cleaning method for all components that are used in the sterile field.

MicroTest Steam Efficacy

Demonstrating efficacy at the US steam sterilization cycle (4 minutes at 132 degrees C, 20 minute dry time).

4 double wrapped packs per load:

- Transducer and Nosecone
- Ultem Nose-cone
- Torque Wrench
- Probes and Stylets

Dry Time Validation

Demonstrating adequate 20 minute dry time for a US steam sterilization cycle.

4 double wrapped packs per load:

- Transducer and Nosecone
- Ultem Nose-cone

- Torque Wrench
- Probes and Stylets

Conclusion

The performance testing summarized above demonstrates that the ShockPulse-SE Lithotripsy System (CYBERWAND II) is substantially equivalent to the predicate device.